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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,340	11/20/2003	Rory F. Finn	01449/1	3646
45734	7590	09/11/2007		
SENNIGER POWERS (PHA) ONE METROPOLITAN SQUARE 16TH FLOOR ST. LOUIS, MO 63102			EXAMINER AUDET, MAURY A	
			ART UNIT 1654	PAPER NUMBER
			NOTIFICATION DATE 09/11/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No. 10/718,340	Applicant(s) FINN, RORY F.	
	Examiner Maury Audet	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 15 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 15 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/13/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response of 6/5/07 is acknowledged. Claims 1-9, 15 and new claims 21-24 are pending and examined on the merits.

Election/Restrictions

As noted before, Applicant's election with traverse of Group I, claims 1-9 and 15, and the species $m=3$, $n=4$, and R =human growth hormone, in the reply filed on 09/18/2006 is acknowledged. The traversal is on the ground(s) that it would not be a serious burden to search Groups I and II. This is not found persuasive for the reasons of record. However, should allowable subject matter be found in the Group I conjugate/composition, then Group II may be considered for rejoinder under *In re Ochiai*, if narrowed to the identical scope. Claims 10-14 and 16-20 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-9 and 15 are examined on the merits as being drawn to the elected invention, and the species $m=3$, $n=4$, and R =human growth hormone.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112 1st Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 15 and new claims 21-24 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

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way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

Applicant's arguments have been considered but are not found persuasive based on the new amendments to the claims.

The claimed invention is drawn to a biPEG-linking structure-monopegHGH/mHGH conjugate and composition thereof; wherein as amended, the HGH (or mHGH) at the R loci is now also monopegylated.

One of skill in the art would not recognize from the disclosure that the Applicant was in possession of the claimed genus of PEG-linking structure-HGH, wherein HGH is monopegylated. Applicant's does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116). Namely, although the claims have been amended in an attempt to overcome the previous issues under written description for the claimed compound formula, new issues are presented by the amendments. Namely, the description is not clear as where the HGH or mHGH at the R loci is

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to monopegylated, or if -NH- to the left of the -R is the N-terminus of said HGH or mHGH or merely an amino group attached e.g. to the C-terminus of said HGH or mHGH? The monopeg should be inserted into the formula at it's appropriate position to the left or right of -R (HGH or mHGH) or to the left of the -NH- group to the left of the -R. Appropriate clarification, with support, is needed. [See 112 2nd below, for related issue].

Thus, a complete conjugated structure as contemplated is lacking in the claims, and arguably in the specification. Absent a complete structure in the claims, a reasonable search could not be conducted, nor would one of skill in the art be apprised of the invention and whether or not other variants read thereon. Thus, neither the claims nor the specification adequately describe the claimed genus of the formula, in order to carry out the invention. One of skill in the art would not recognize from the disclosure that the Applicant was in possession of the genus, namely biPEG-linking structure-monopegHGH/mHGH.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 15, and new claims 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In e.g. amended claim 1, the formula has been textually amended to now read that HGH or mHGH is monopegylated at the N-terminus. However, if this is so, then an "mPEG" needs to be inserted into the formula either directly left of the "R" (HGH or mHGH) or directly left of the

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"NH-R", if the NH is deemed to be the amino terminal of the HGH or mHGH contemplated at loci R. The actual structure of the formulated compound as amended remains unclear and a reasonable and proper search is still not possible.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 8/28/2007



CHRISTOPHER R. TATE
PRIMARY EXAMINER